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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/076,069      | 02/15/2002  | Roland Jurecic       | 39532-176599        | 8513             |

26694 7590 01/27/2003

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| EXAMINER |
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BERTOGLIO, VALARIE E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1632

DATE MAILED: 01/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/076,069

Applicant(s)

JURECIC ET AL.

Examiner

Valarie Bertoglio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to an isolated nucleic acid comprising a sequence that is at least 85% identical to SEQ ID NO: 1, classified in class 536, subclass 23.1.
- II. Claims 1-10, drawn to an isolated nucleic acid comprising a sequence that is at least 85% identical to SEQ ID NO: 3, classified in class 536, subclass 23.1.
- III. Claims 11-18, drawn to an isolated polypeptide comprising an amino acid sequence that is at least 60% similar to SEQ ID NO: 2 or SEQ ID NO: 6, classified in class 530, subclass 350.
- IV. Claims 11-18, drawn to an isolated polypeptide comprising an amino acid sequence that is at least 60% similar to SEQ ID NO: 4 or SEQ ID NO: 7, classified in class 530, subclass 350.
- V. Claims 11-18, drawn to an isolated polypeptide comprising an amino acid sequence that is at least 60% similar to SEQ ID NO: 5, classified in class 530, subclass 350.
- V. Claims 19-22, drawn to a mutant mammal having germ and/or somatic cells that carry at least one copy of an impaired HEPP gene, classified in class 800, subclass 14.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the nucleic acid molecules of each invention are materially and structurally distinct and have distinct use. The nucleic acid of each invention encodes a different polypeptide that may function differently in vivo or in vitro

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assays and provide different therapeutic value. The nucleic acids of each invention are functionally distinct and neither is required for the other. Furthermore, because the nucleic acids of each invention are drawn to different SEQ ID NO.s with that differ substantially in sequence, a separate search would be required for each invention. Therefore, the burden required to search Inventions I and II together would be undue.

Inventions I or II and Inventions III, IV, or V are patentably distinct because, the nucleic acids of Inventions I and II differ materially, in function and in use from the proteins of Inventions III-V. The nucleic acids of Inventions I and II can be used as a DNA probe while the proteins of Inventions III-V can be used to generate antibody. The protocols and reagents required for the nucleic acids and the proteins are materially distinct and separate. The burden required to search Inventions I or II and Inventions III, IV or V together would be undue.

Inventions I or II and Invention VI are patentably distinct because, the nucleic acids of Inventions I and II differ materially, in function and in use from the animal of Invention VI. The nucleic acids of Inventions I and II can be used as a DNA probe while the animal of Invention VI can be used study the in vivo role of Hepp. The protocols and reagents required for the nucleic acids and the animal are materially distinct and separate. The burden required to search Inventions I or II and Invention VI together would be undue.

Inventions III, IV and V are patentably distinct because the proteins of each invention are materially and structurally distinct and have distinct use. The protein of each invention is functionally distinct and neither is required for the other. Furthermore, because the polypeptides of each invention are drawn to different SEQ ID NO.s with that differ substantially in sequence, a separate search would be required for each invention. Therefore, the burden required to search Inventions III, IV and V together would be undue.

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Inventions III, IV or V and Invention VI are patentably distinct because, the proteins of Inventions III, IV and V differ materially, in function and in use from the animal of Invention VI. The proteins of Inventions III, IV and V can be used to generate antibodies to Hepp proteins while the animal of Invention VI can be used study the in vivo role of Hepp. The protocols and reagents required for the proteins and the animal are materially distinct and separate. The burden required to search Inventions III, IV or V and Invention VI together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the searches for the groups are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

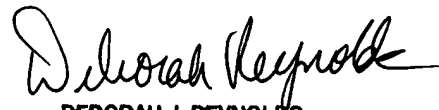
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio  
Patent Examiner



DEBORAH J. REYNOLDS  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600